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2022 NOV 1 AM 11:07  
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U.S. DISTRICT COURT

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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF UTAH

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UNITED STATES OF AMERICA,

Plaintiff,

vs.

DEWAYNE LEE SMITH,

Defendant.

**MISDEMEANOR INFORMATION**

Counts 1-3: 21 U.S.C. § 331(a)  
(Introduction of Misbranded Drugs into  
Interstate Commerce)

**Case: 2:22cr00424**

**Assigned To : Romero, Cecilia M.**

**Assign. Date : 11/1/2022**

**Description: USA v Smith**

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The United States alleges:

**Count 1**

**21 U.S.C. § 331(a)**

**(Introduction of Misbranded Drugs into Interstate Commerce)**

On or about May 22, 2018, in the District of Utah and elsewhere,

**DEWAYNE LEE SMITH,**

defendant herein, using his companies The Delta Institute, Delta Member Services, Inc., and Somerset Falls, LLC, introduced, delivered for introduction, and caused the introduction and delivery for introduction into interstate commerce, from the state of Utah to Nevada, drugs, as defined at Title 21, United States Code, Section 321(g), to wit: Bx Protocol, which were misbranded in that:

- a. The labeling was false and misleading, in that it was represented to be a dietary

supplement (21 U.S.C. § 352(a));

- b. They were manufactured, prepared, propagated, compounded, and processed in an establishment not duly registered as a drug manufacturer with Food and Drug Administration (21 U.S.C. § 352(o));
- c. Their labeling failed to bear adequate directions for use (21 U.S.C. § 352(f)(1)); and
- d. They did not bear a label containing the name and place of business of the manufacturer, packer, or distributor, including the street address, city and zip code. (21 U.S.C. § 352(b)(2) and 21 C.F.R. § 201.1(i)).

All in violation of 21 U.S.C. §§ 331(a) and 333(a)(1), and 18 U.S.C. § 2.

**Count 2**  
**21 U.S.C. § 331(a)**  
**(Introduction of Misbranded Drugs into Interstate Commerce)**

On or about September 18, 2018, in the District of Utah and elsewhere,

**DEWAYNE LEE SMITH,**

defendant herein, using his companies The Delta Institute, Delta Member Services, Inc., and Somerset Falls, LLC, introduced, delivered for introduction, and caused the introduction and delivery for introduction into interstate commerce, from the state of Utah to Illinois, drugs, as defined at Title 21, United States Code, Section 321(g), to wit: Bx Protocol, which were misbranded in that:

- a. The labeling was false and misleading, in that it was represented to be a dietary supplement (21 U.S.C. § 352(a));
- b. They were manufactured, prepared, propagated, compounded, and processed in an establishment not duly registered as a drug manufacturer with Food and Drug Administration (21 U.S.C. § 352(o));
- c. Their labeling failed to bear adequate directions for use (21 U.S.C. § 352(f)(1)); and
- d. They did not bear a label containing the name and place of business of the manufacturer, packer, or distributor, including the street address, city and zip code. (21 U.S.C. § 352(b)(2) and 21 C.F.R. § 201.1(i)).

All in violation of 21 U.S.C. §§ 331(a) and 333(a)(1), and 18 U.S.C. § 2.

**Count 3**  
**21 U.S.C. § 331(a)**  
**(Introduction of Misbranded Drugs into Interstate Commerce)**

On or about October 27, 2018, in the District of Utah and elsewhere,

**DEWAYNE LEE SMITH,**

defendant herein, using his companies The Delta Institute, Delta Member Services, Inc., and Somerset Falls, LLC, introduced, delivered for introduction, and caused the introduction and delivery for introduction into interstate commerce, from the state of Utah to Washington, drugs, as defined at Title 21, United States Code, Section 321(g), to wit: Bx Protocol, which were misbranded in that:

- a. The labeling was false and misleading, in that it was represented to be a dietary supplement (21 U.S.C. § 352(a));
- b. They were manufactured, prepared, propagated, compounded, and processed in an establishment not duly registered as a drug manufacturer with Food and Drug Administration (21 U.S.C. § 352(o));
- c. Their labeling failed to bear adequate directions for use (21 U.S.C. § 352(f)(1)); and
- d. They did not bear a label containing the name and place of business of the manufacturer, packer, or distributor, including the street address, city and zip code. (21 U.S.C. § 352(b)(2) and 21 C.F.R. § 201.1(i)).

All in violation of 21 U.S.C. §§ 331(a) and 333(a)(1), and 18 U.S.C. § 2.

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